

## REMARKS

Claims 1-11 and 17-25, as amended, and new claims 26-30 are now pending for the Examiner's consideration. New claims 26-30 are identical to claims 12-16 at the time they were previously canceled to expedite prosecution. Claim 1 has been amended to clarify that the grasping portions extend a greater transverse distance than the flared portion (*See, e.g.*, FIGS. 2-3). Claim 17 has been amended to clarify that the gender-identifying color association with the clamp remains to facilitate identification of the gender of the baby while the clamp remains on the baby's cord stump (*See, e.g.*, Specification at page 10, lines 25-28). No new matter has been added by way of these amendments or new claims, such that their entry at this time is warranted.

Claims 1-8 and 10 are now rejected under 35 U.S.C. § 102(b), as being anticipated by U.S. Patent No. 5,006,830 to Merritt ("Merritt") on pages 2-3 of the Office Action. The Office Action states that Merritt teaches a flared portion (21,22) at the end of each arm and a grasping portion (28,32), and that the fact that flared portions are of better size and shape is not evidence that the grasping portions are not also each capable of receiving a finger. The Office Action alleges that the grasping portions are inherently sufficiently sized and shaped to receive a "tool" since virtually any size or shape arm portion can do so, *e.g.*, pliers. The Office Action does, however, concede that Merritt is silent as to using the grasping portions for the claimed purposes.

Initially, the Office Action is clearly incorrect about the ability of Merritt's "grasping portion" (28,32) to suitably receive a tool. As noted in the background of the application, conventional clamps are difficult to close and lock, particularly due to the fluids present that create slippery conditions at the clamp and on the hands of the birth assistant, *e.g.*, doctor, midwife, nurse, *etc.* (Specification at page 2, lines 27-29). Merritt suffers from this problem. To make matters worse, Merritt discloses that its' "grasping portion" is actually an enlarged oval-shaped portion 32 on which a distinctive identification mark 30 is provided. This mark 30 may be an integrally formed *raised serial number* or other mark (Col. 4, lines 10-14). Naturally, applying the pressure of a tool to a narrow raised portion of a resilient object is highly unstable, and actually would facilitate tool slippage if pressure were applied to close the clamp as suggested in the Office Action. Thus, Merritt fails to disclose or suggest a grasping portion so as to facilitate grasping and closing of the clamp, as presently recited. In fact, Merritt is missing the claimed feature and actually *teaches away* from the claimed invention by disclosing an oval-shaped portion for identification purposes, which adversely affects the ability to close the clamp using force at that location on the clamp arms.

Moreover, claim 1 has been amended to more clearly and distinctly recite the invention wherein the grasping portion extends a greater transverse distance than the flared

portion away from the arm. This clarifies that the grasping portion must extend outwardly from the arm. Merritt clearly only discloses an oval-shaped area with raised serial numbers or other markings for identification, but it fails to teach a grasping portion that extends transversely, as presently recited. For any of these reasons, Merritt fails to disclose or even suggest each and every claimed feature. As such, Applicant respectfully requests that the rejection of claims 1-8 and 10 under 35 U.S.C. § 102(b) be reconsidered and again withdrawn.

Claims 9 and 11 were rejected under 35 U.S.C. § 102(b) as being obvious over Merritt on pages 3-4 of the Office Action. The Examiner states that, although Merritt does not disclose the features of claims 9 or 11, Applicant has not shown any criticality to these dimensions and the device would work equally well with any given dimensions. As to the location of the grasping portion, the Office Action states that this could be placed anywhere along the length of the arms.

On the contrary, the grasping portions cannot be "placed anywhere along the length of the arms" as alleged by the Patent Office. Placing the grasping portions too close to the rear end portion of the clamp requires significantly greater force and therefore increases the risk of slippage while closing the clamp. Thus, the assumption in the Office Action is incorrect with respect to claim 9. Claim 11 recites a particular transverse distance, which is clearly not taught by Merritt's identification portion. Indeed, as previously discussed, Merritt *teaches away* from the dimensions and location that facilitate grasping and closing of the clamp, as presently recited in claim 11. Moreover, Merritt *teaches away* from the claimed invention by disclosing the oval-shaped portion for identification purposes, which appears to include an instability **increasing** raised portion that would adversely affect the ability of the clamp to be closed.

More importantly, Merritt fails to attach any significance to the location of its identification portion, nor would it. Merritt suggests the identification oval can be placed anywhere because it is simply a visual feature, while claims 9 and 11 recite particular dimensions and locations because these are important to the surprisingly and unexpected solution of clamp/tool slippage during closing. Thus, one of ordinary skill in the art, aware of Merritt, would not have been motivated to modify its identification portion to obtain the size, shape, or location of the claimed grasping portion, as presently recited in claims 9 and 11, since Merritt teaches a completely different structure compared than presently recited. Moreover, those of ordinary skill in the art, aware of the inclusion of a raised, oval-portion as taught by Merritt, would not have expected to achieve success in obtaining the surprising and beneficial clamp structure presently recited. For these reasons, claims 9 and 11 are not even suggested by the cited prior art of record, and they provide a surprising and unexpected benefit that provides an elegant solution to the clamp/tool slippage problem—which Merritt completely fails to recognize. As such, Applicant

respectfully requests that the rejection of claims 9 and 11 under 35 U.S.C. § 103(a) be reconsidered and withdrawn since no *prima facie* case of obviousness has been shown on the record.

Claims 17-25 were also rejected under 35 U.S.C. § 103(a) as being obvious over Merritt in view of U.S. Patent No. 6,132,447 to Dorsey ("Dorsey") on pages 3-4 of the Office Action. The Office Action states Merritt provides all the features of claim 17 except the gender-identifying color associated with a portion of the clamp. The Office Action relies on Dorsey, which allegedly evidences use of a device to provide umbilical devices with gender-identifying color coding for readily recognizable indicia associated with newborns, and that this would have been recognized as being readily adapted for umbilical cord severing.

On the contrary, Dorsey is directed to a completely distinct article--blue or pink labeled scissors used to cut the umbilical cord. Dorsey's scissors do not remain with the newborn, but are separately packaged and provided in a nice display for the parents. At best, Dorsey provides a novelty toy to new parents, or perhaps a souvenir of the baby's birth in the hospital. Dorsey does not, however, teach anything regarding providing a gender-identifying means that is clamped onto the newborn or otherwise associated with a portion of the clamp to facilitate identification of the gender of the baby. Claim 17 has also been amended to clarify that the gender-identifying means is present while the clamp remains on the baby's cord stump, *i.e.*, the gender-identifying means remains with the baby until the umbilical cord and/or clamp fall off or are physically removed. Dorsey's colored scissors are never on the baby's cord stump, as presently recited, as they are simply used momentarily to cut the umbilical cord.

Merritt discloses an identification system to deter the unauthorized removal of a newborn from a defined area, while Dorsey provides blue or pink scissors to cut a baby's umbilical cord. Aside from both generally relating to the birthing experience, the references themselves contain absolutely no motivation whatsoever to suggest to one of ordinary skill in the art that they could have been combined in some way. Indeed, Merritt discloses a clamp that contains particular types of identification marks including a serial code, bar code, color code, or letter combination, each of which has a different distinctive mark thereon (Col. 4, lines 10-24). Merritt fails to disclose the inclusion of a color, including shades thereof, to provide identification means comprising a gender-identifying color to facilitate identification of the gender of a newborn baby, as presently recited. At best, it discloses a *color code* to prevent unauthorized removal of a newborn from a pre-defined area. Thus, Merritt requires a color code, which is presumably at least a pattern of multiple colors, to provide identification for its stated purpose of preventing unauthorized removal.

Thus, Dorsey *teaches away* from Merritt, because Merritt discloses that every clamp should have a different distinctive identification mark thereon. Dorsey, however, teaches use of the pink and blue coatings on its scissors to identify gender (Col. 2, lines 13-27), and this is not a sufficient universe of colors to create a "color code" or to uniquely and distinctly identify every newborn in a given hospital or health care facility as required by Merritt. While Dorsey does teach other colors like green and yellow, these are used when the baby's gender is undetermined. As such, one of ordinary skill in the art would not have been motivated to combine Dorsey and Merritt prior to the time of the surprising and unexpected invention presently claimed.

As discussed in the remarks of a previous submission to the Patent Office, no motivation existed for one of ordinary skill in the art to have made colored clamps to identify gender, or to modify clamps in this way based on traditional use of clothing to identify gender. The surprising and unexpected advantages of the claimed invention relative to conventional gender identification (Specification at page 10, lines 17-28) are clear in view of the present specification. Conventional colored clothing has a tendency to fall off babies as any parent will know, and the wrong colored bonnet could easily be applied to a fully-clothed baby (*e.g.*, by an overworked, exhausted health care provider). The present invention, however, elegantly solves this problem by applying a gender-identifying clamp to a nude newborn at birth--when the chance for gender misidentification is significantly lower than later times when clothes are worn. The clamp of the invention does not typically fall off, either, and remains with the diapered-newborn baby until the cord falls off, which is generally after the baby departs from the hospital or other pre-defined area. The simple fact is that millions of babies are delivered annually, and to the Applicant's knowledge no one has ever achieved such a simple, elegant solution to the problem of gender misidentification of newborn babies. In fact, it should be clear common sense that there is a long-felt need in the obstetric art for the improved gender-identifying clamp provided by the claimed invention. For these and other reasons, the rejection under 35 U.S.C. § 103(a) has been overcome and should be reconsidered and withdrawn, particularly since no *prima facie* case of obviousness has been stated on the record even in view of the combination of cited references.

New claims 26-30 are identical to prior claims 12-16, which were canceled to expedite the allowance of this application. In view of the Patent Office withdrawing the Notice of Allowance, however, Applicant now adds these claims for further prosecution and discusses the patentability of these claims with respect to the rejection previously imposed on these claims.

With respect to claims 26-30, Merritt does not disclose or even suggest that the channel in each arm is open at the end. Merritt simply teaches that a groove is present in a

portion of each arm along a portion of the length of each arm *to prevent the clamp from slipping off the umbilical cord*. The prior Office Action referred to features 23,24, which is clearly a groove in FIG. 6 and discussed at Col. 3, lines 54-63 of Merritt. FIG. 6 of Merritt is merely a cross-section, however, this does not teach anything regarding the open or closed nature of the ends of the channels. Rather, it is clear from the dashed lines in FIG. 1 that this groove **does not extend** along the full length of each arm in Merritt. In fact, Merritt's FIG. 1 explicitly teaches that the groove in each arm terminates so that it is closed at each end of the arm.

On the contrary, claim 26 of the present invention clearly recites that the channel is open at the free end to facilitate the escape of fluid therefrom when the clamp is closed according to the present invention. Since Merritt fails to disclose an open-ended channel at the free end of an arm, nor would it need to for its desired purpose of having the clamp close more effectively onto the cord, Merritt cannot anticipate or even suggest the invention of claims 26-30. Moreover, Merritt fails to disclose that the channel is open to a lateral groove disposed between the teeth and the tongue, as recited by claim 30. For these reasons, Merritt does not teach claims 26-30.

As for claims 28-29, which are dependent from claim 26, Merritt completely fails to suggest the removal of fluids, and its structure would not inherently do so (See FIG. 1, dashed lines). Also, the size and shape of the channel, as recited in claims 28-29, are each important to the claimed invention whereby the channel facilitates removal of fluids from the clamp when it is closed. Merritt only teaches that a closed channel can be included to help grip the umbilical cord when the clamp is closed. Thus, no motivation existed based on the teaching of Merritt for one of ordinary skill in the art to have modified the presently recited channel, absent an improper hindsight review using the present specification.

Those of ordinary skill in the art, based on Merritt, would not have reasonably expected to achieve the surprising and unexpected result of the invention presently recited by claims 26-30. The open channel presently claimed helps remove fluids from the area near the umbilical cord clamp, which accelerates and promotes drying of the cord to facilitate its removal and also minimizes the risk of infection from any bacterial or viral agents in the fluids. Merritt's structure does not facilitate removal fluids from the area around the cord, and thus, Merritt has completely failed to recognize the surprising and unexpected benefits that can be achieved using the presently recited structure. Indeed, Merritt simply does not suggest to the ordinary-skilled artisan to have open channels run clear to the end of an arm of the clamp, and would not have expected to achieve the success of the claimed invention. For these reasons, Applicant respectfully submits that claims 26-30 are patentable and should stand allowed.

Accordingly, Applicant submits that all claims are again in condition for allowance. Should the Examiner not agree with this position, a telephone or personal interview is requested to resolve any remaining issues and expedite allowance of this application, e.g., by Examiner's Amendment.

Respectfully submitted,

April 9, 2004  
Date

Jeffrey A. Wolfson  
Jeffrey A. Wolfson (Reg. No. 42,234)

**WINSTON & STRAWN LLP**  
**Customer Number: 28765**

(202) 371-5770